

### **REMARKS**

Applicant respectfully requests reconsideration. Claims 14, 15 and 18-28 were previously pending in this application. By this amendment, Applicant is canceling claims 15, 20 and 21 without prejudice or disclaimer. Claim 14 has been amended to include the features of claim 15, to recite particular cannabinoids (CBC and/or CBC-V), and to recite a particular amount of the cannabinoids CBC and/or CBC-V. Support for the amendments to claim 14 is found in the claims as previously pending, and throughout the specification as filed, for example at page 4, lines 19-20 and page 6, lines 4-8. Claims 18, 22-24 and 26 have been amended to be consistent with the amendments made to claim 14. As a result, claims 14, 18, 19 and 22-28 are pending for examination with claim 14 being an independent claim.

The structures for Formulas 1, 2 and 3 in the specification have been amended to correct obvious errors in the chemical structures. Applicant also submits herewith a replacement Fig. 1 to correct an obvious error in a chemical structure.

No new matter has been added.

### **Summary of Interview**

Applicant thanks the Examiner for the telephonic interview conducted on August 18, 2009 with the undersigned and representatives of the assignee. Amendments to the claims were proposed to overcome the obviousness rejections, and the differences between the amended claims and the prior art of record were discussed. Applicant's representative also discussed that the amendments to the claims resulted in significant differences between the claims as amended and the claims of 11/760,364 such that the double patenting rejection was no longer applicable.

**Rejections Under 35 U.S.C. § 103**

1. The Examiner rejected claims 14-15 and 18-28 under 35 U.S.C. § 103(a) as being unpatentable over Brooke et al. (U.S. Patent 6,328,992) in view of Travis (U.S. Patent 6,541,510) and Turner et al. (J. Clin. Pharmacol. 1981; 21:283S-291S). Applicant respectfully traverses the rejection.

**The cited prior art does not provide all of the elements of the claimed invention**

Brooke et al. states that several medicinal uses have been found for cannabis as useful potentially for treating stress and depression (col. 1, line 32). Brooke et al. also states that THC is the “primary active ingredient of cannabis” (col. 1, lines 42-44).

Brooke et al. does not comment on the activity of other cannabinoids. In particular, Brooke et al. does not disclose that cannabichromene (CBC) and/or cannabichromene propyl analogue (CBC-V) is useful for treating mood disorders.

Brooke et al. also does not disclose that CBC and/or CBC-V is present as more than 30% of the cannabinoids in the composition, as is now claimed. Applicant submits that the Whittle Declaration (previously filed) supports that the level of CBC is very low in mature plants and certainly lower than the claimed amount, see, e.g., paragraphs 7.1-10 of the Whittle Declaration.

The Travis reference and the Turner et al. reference do not provide the elements of the claims that are absent from Brooke et al., and indeed the Examiner has cited Travis for its asserted teaching of cannabichromene compounds of formula 1 and has cited Turner et al. for its asserted teaching that cannabichromene is a crude drug made from cannabis plants. Neither reference, however, teaches or suggests using cannabichromene for treatment of mood disorders.

Therefore, the cited combination of prior art references does not provide all of the elements of the claimed invention.

Motivation to combine the cited references and a reasonable expectation of success are absent

Applicant submits that there are dozens of cannabinoids known in cannabis (see, e.g., Wikipedia entry at [<http://en.wikipedia.org/wiki/Cannabinoid>], a copy of which is included herewith). In particular, this document shows the existence of 68 cannabinoids (see “Table of natural cannabinoids” at pages 7-10) and reports on page 2 that “At least 66 cannabinoids have been isolated from the cannabis plant (see page 2, citing to reference 4, Burns and Ineck, *Annals Pharmacother.*, 40:251-260, 2006). Therefore, absent some teaching pointing to specific cannabinoids, the skilled person would not have known which one or more cannabinoids would be useful in treating mood disorders, and would not have had a reasonable expectation of success in randomly selecting cannabinoids to try.

The MPEP states that the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. MPEP 2144.08 II, citing *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Therefore, absent some indication in the prior art that cannabichromene and/or cannabichromene propyl analogue in particular is/are useful for treating mood disorders, the claims are not obvious in view of combination of Brooke et al., Travis and Turner et al.

In addition, the skilled person would not have been motivated to make the claimed invention due to the link between cannabis and depression in the art as was stated in the previously-filed Whittle Declaration (see paragraph 11c). Dr. Whittle also stated that the skilled person would not have had a reasonable expectation of success in making the claimed invention for this same reason.

Accordingly, Applicant respectfully requests withdrawal of the rejection.

2. The Examiner rejected claims 14-15 and 18-28 under 35 U.S.C. § 103(a) as being unpatentable over Whittle et al. (U.S. Pub. 2005/0042172) in view of Travis (U.S. Patent 6,541,510). Applicant respectfully traverses the rejection.

The cited prior art does not provide all of the elements of the claimed invention

The Examiner states at page 7 of the Office Action that it would have been obvious to treat mood disorders such as depression with cannabichromene compounds because Whittle allegedly teaches that cannabichromenes are useful for treating disorders such as pain associated with depression, which necessarily treat depression. Applicant respectfully disagrees.

Whittle at paragraph [0056] teaches that compositions comprising cannabis extracts, natural or synthetic cannabinoids or mixtures thereof can be administered “in the form of a vapour for the treatment of pain, particularly pain unresponsive to opioid analgesics, pain arising from neuropathic and neurogenic conditions, dysmenorrhoea, inflammatory pain, particularly that associated with rheumatoid arthritis, depression, migraine, asthma, epilepsy, post-operative pain, glaucoma, chemotherapy-induced nausea and vomiting, relief of pain and muscle spasm in multiple sclerosis, and loss of appetite and anorexia, particularly in AIDS patients.” That passage is the only mention of treatment of depression in the Whittle application.

Importantly, Whittle does not link any specific cannabinoid to treatment of depression, and more importantly, does not link the use of CBC to treatment of depression.

Whittle also does not disclose that CBC and/or CBC-V is present as more than 30% of the cannabinoids in the composition, as claimed. As noted above and supported by the previously filed Whittle Declaration, the level of CBC is very low in mature plants and certainly lower than the claimed amount, see, e.g., paragraphs 7.1-10 of the Whittle Declaration.

The Travis reference does not provide the elements of the claims that are absent from Whittle, and indeed the Examiner has cited Travis for its alleged teaching of compounds of formula 1.

Therefore, the cited combination of prior art references does not provide all of the elements of the claimed invention.

Motivation to combine the cited references and a reasonable expectation of success are absent

As noted above, Applicant submits that there are dozens of cannabinoids known in cannabis (see, e.g., Wikipedia entry at [<http://en.wikipedia.org/wiki/Cannabinoid>], a copy of which is included herewith). In particular, this document shows the existence of 68 cannabinoids (see “Table of natural cannabinoids” at pages 7-10) and reports on page 2 that “At least 66 cannabinoids have been isolated from the cannabis plant (see page 2, citing to reference 4, Burns and Ineck, *Annals Pharmacother.*, 40:251-260, 2006). Therefore, absent some teaching pointing to specific cannabinoids, the skilled person would not have known which one or more cannabinoids would be useful in treating mood disorders, and would not have had a reasonable expectation of success in randomly selecting cannabinoids to try.

The MPEP states that the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. MPEP 2144.08 II, citing In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Therefore, absent some indication in the prior art that cannabichromene and/or cannabichromene propyl analogue in particular is/are useful for treating mood disorders, the claims are not obvious in view of combination of Whittle and Travis.

In addition, the skilled person would not have been motivated to make the claimed invention due to the link between cannabis and depression in the art as was stated in the previously-filed Whittle Declaration (see paragraph 11c). Although his Declaration was submitted to rebut the teachings of the Brooke et al. patent, the statement made by Dr. Whittle in paragraph 11c also applies equally to other combinations of prior art, including the combination of Whittle and Travis. Dr. Whittle also stated that the skilled person would not have had a reasonable expectation of success in making the claimed invention for this same reason.

Accordingly, Applicant respectfully requests withdrawal of the rejection.

**Double Patenting Rejection**

The Examiner provisionally rejected claims 14-15, 18-25 and 27-28 on the ground of non-statutory obviousness-type double-patenting as being unpatentable over claims 1-5, 12 and 14 of co-pending Application No. 11/760,364.

The instant claims have been amended to recite administration of CBC and/or CBC-V, wherein the CBC and/or CBC-V is substantially pure or is an extract from a cannabis plant that contains greater than or equal to 30% CBC and/or CBC-V of the total cannabinoid content

The claims in US 11/760,364 are being amended to recite administration of entirely different cannabinoids, cannabigerol (CBG), cannabigerol propyl analogue (CBGV) and/or cannabigerol-dimethyl heptyl, which are structurally different than the compounds recited in the claims as amended of the instant application. The use of the two recited compounds for treating mood disorders is not obvious in view of the use of CBC, CBCV and/or cannabigerol-dimethyl heptyl in US 11/760,364.

Accordingly, Applicant submits that there is no obviousness-type double patenting between US 11/760,364 and the instant application, and Applicant respectfully requests that the Examiner withdraw this rejection.

### **CONCLUSION**

In view of the above amendment, Applicant submits that the pending application is in condition for allowance. A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. B0192.70062US00.

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Respectfully submitted,  
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